



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

March 26, 2020

Wendy A. McCombie  
Agent with Lewis & Harrison, LLC  
Celeste Industries Corp  
2461 South Clark Street, Suite 710  
Arlington, VA 22202

Subject: Label Amendment – Emerging Viral Pathogens Claim  
Product Name: Sani-Cide EX3 (10X) RTU  
EPA Registration Number: 42048-4  
Application Date: February 15, 2020  
Decision Number: 560788

Dear Wendy:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), [https://www.epa.gov/sites/production/files/2016-09/documents/emerging\\_viral\\_pathogen\\_program\\_guidance\\_final\\_8\\_19\\_16\\_001\\_0.pdf](https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf), you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
  - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
    - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
      - A. CDC Current Outbreak List for “U.S. Based Outbreaks” ([www.cdc.gov/outbreaks](http://www.cdc.gov/outbreaks)),
      - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification ([www.cdc.gov/outbreaks](http://www.cdc.gov/outbreaks)) (also released through the CDC’s Health Alert Network (HAN) notification process)
      - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page ([www.cdc.gov/hai/outbreaks](http://www.cdc.gov/hai/outbreaks))
    - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page ([www.oie.int/wahis\\_2/public/wahid.php/Diseaseinformation/WI](http://www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI)).
  - b. The virus is a large non-enveloped and enveloped virus.
    - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is large non-enveloped and enveloped.
    - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Feline Calicivirus is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact disinfectants list at [disinfectantslist@epa.gov](mailto:disinfectantslist@epa.gov).

Sincerely,



John Hebert, Chief  
Regulatory Management Branch 1  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

Enclosure: stamped label

**ACCEPTED**

**03/26/2020**

Under the Federal Insecticide, Fungicide  
and Rodenticide Act as amended, for the  
pesticide registered under  
EPA Reg. No. 42048-4

## **SANI-CIDE EX3 (10X) RTU**

**{Alternate Brand Name: Sani-Cide EX3}**

**Ready-to-Use Broad Spectrum Disinfectant and Cleaner**

**For Use on Airplane Hard Non-Porous Surfaces**

***{Note to Reviewer: this fragrance descriptor may be used for product formulated without fragrances:}***  
**FRAGRANCE FREE**

### Active Ingredient

L-Lactic Acid..... 0.40%

Inert Ingredients ..... 99.60%

Total 100.00%

**KEEP OUT OF REACH OF CHILDREN**

## **CAUTION**

[See (inside) (back) (side) (panel) for Additional Precautionary Statements (and First Aid)]

### First Aid

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

### Hot Line Number

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-424-9300 for emergency medical treatment information.

EPA Reg. No. 42048-4

EPA Est. No. 42048-MD-001

Net Contents:

***{Note to Reviewer: The batch code number may appear on the label or on the individual container}***

Batch Code:

Manufactured by: Celeste Industries Corp., [+1.410.822.5775.] 8221 Teal Drive, Suite 405, Easton, MD 21601

### Precautionary Statements

Hazards to Humans and Domestic Animals

Caution. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

### Environmental Hazards

*[If container size is 5 gallons or greater the following statement will be used:]*

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

### **Directions for Use**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Use Sani-Cide EX3 (10X) RTU to disinfect airplane hard non-porous surfaces such as tray tables, armrests, lavatory door handles, galley workspaces and on any other objects or surfaces which passengers and crew may come in contact with. Sani-Cide EX3 (10X) RTU is an effective disinfectant against *Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708), *Pseudomonas aeruginosa* (ATCC 15442), Human Norovirus (Feline Calicivirus (ATCC VR-782, Strain F9, surrogate for human norovirus), Methicillin Resistant *Staphylococcus aureus* (ATCC 33592), Influenza A virus (ATCC VR-544, Strain A/Hong Kong/8/68), Influenza B virus (ATCC VR-823, Strain B/Hong Kong/5/72).

### **Application Instructions:**

Prior to disinfection, pre-clean hard non-porous surfaces by spraying Sani-Cide EX3 (10X) RTU directly on to the surface. Spray 6-8 inches from surface then wipe with a cloth and let dry.

To disinfect, spray Sani-Cide EX3 (10X) RTU directly on to the hard non-porous surface. Spray 6-8 inches from surface. Treated surfaces must remain wet for 10 minutes. After 10 minutes, wipe (dry if desired) with a cloth and let dry.

### **STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.

**Product Storage:** Store in a cool, dry, well-ventilated area inaccessible to children. If leak or spill occurs – ventilate area of leak or spill. Remove all sources of ignition. Dilute with water and mop-up or absorb with an inert material (e.g., vermiculite, dry sand, earth) and place in a chemical waste container.

**Product Disposal:** Wastes resulting from the use of this product must be disposed of on-site or at an approved waste disposal facility.

**Container Disposal:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If recycling is not available, place empty container in trash or dispose of in a sanitary landfill.

[Optional Non-Pesticidal Marketing Language]

- Sani-Cide EX3 (10X) RTU will NOT discolor hard, non-porous surfaces in airplane cabins.
- Sani-Cide EX3 (10X) RTU has been tested according to (complies with) Aerospace Material Specification (AMS) 1550B, 1452C and Boeing D6-7127 test specifications.

[Optional Pesticidal Marketing Language]

- Sani-Cide EX3 (10X) RTU is a broad spectrum disinfectant and All-purpose Cleaner which leaves surfaces with a Streak-Free appearance and leaves a fresh pleasant scent.
- Use Sani-Cide (10X) RTU on hard, non-porous surfaces in airplane cabins where bacteria or strong unpleasant odors are likely to be present.

### ***Emerging Viral Pathogen Claims***

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging pathogen claims from the following viral category[ies]:

-Enveloped Viruses

-Large Non-Enveloped Viruses

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped Virus	Feline calicivirus, Strain F-9, ATCC VR-782 (Surrogate for Norovirus)
Large, non-enveloped virus	Feline calicivirus, Strain F-9, ATCC VR-782 (Surrogate for Norovirus)
<p><b>[Product name]</b> has demonstrated effectiveness against viruses similar to <b>[name of emerging virus]</b> on hard, <b>[porous and/or non-porous surfaces]</b>. Therefore, <b>[product name]</b> can be used against <b>[name of emerging virus]</b> when used in accordance with the directions for use against <b>[name of supporting virus(es)]</b> on <b>[hard, porous/non-porous surfaces]</b>. Refer to the <b>[CDC or OIE]</b> website at <b>[pathogen-specific website address]</b> for additional information.</p> <p><b>[Name of illness/outbreak]</b> is caused by <b>[name of emerging virus]</b>. <b>[Product name]</b> kills similar viruses and therefore can be used against <b>[name of emerging virus]</b> when used in accordance with the directions for use against <b>[name of supporting virus(es)]</b> on <b>[hard, porous/non-porous surfaces]</b>. Refer to the <b>[CDC or OIE]</b> website at <b>[website address]</b> for additional information.</p>	